Practitioner's Docket No. U 016325-6

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PATENT TRADEMARK OFFICE

CHAPTER II

TRANSMITTAL LETTER TO THE UNITED STATES ELECTED OFFICE (EO/US) (ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)

INTERNATIONAL APPLICATION NO.

INTERNATIONAL FILING DATE

PRIORITY DATE CLAIMED

PCT/EP2004/014359

16 DECEMBER 2004

19 DECEMBER 2003

TITLE OF INVENTION

THE USE OF CYSTINE OR CYSTEINE FOR THE PREVENTION AND TREATMENT OF OXIDATIVE STRESS CAUSE BY HAEMODIALYSIS AND OF ACUTE OR CHRONIC KIDNEY DISEASES

APPLICANT(S)

SANTANGELO, Francesco

Mail Stop PCT
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

ATTENTION: EO/US

COMPLETION OF FILING REQUIREMENTS FOR INTERNATIONAL APPLICATION ENTERING U.S. NATIONAL STAGE IN U.S. ELECTED OFFICE (EO/US) UNDER 35 U.S.C. § 371

(check and complete the applicable item, if applicable)

- [x] This replies to the Notice of Missing Requirements under 35 U.S.C. § 371 and 37 C.F.R. § 1.495 (FORM PCT/DO/EO/905).
 - [x] A copy of FORM PCT/DO/EO/905 accompanies this response.

CERTIFICATION UNDER 37 C.F.R. 1.10*

(Express Mail label number is mandatory.) (Express Mail certification is optional.)

I hereby certify that this Completion of Filing Requirements and the papers indicated as being transmitted therewith are being deposited with the United States Postal Service on this date <u>March 7, 2007</u>, in an envelope as "Express Mail Post Office to Addressee," Mailing Label Number <u>EV 927 568 381 US</u>, addressed to the: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Geraldine Marti

type or print name of person mailing paper)

....

Signature of person mailing paper

WARNING:

Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

*WARNING:

Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).

"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

(Completion of Filing Requirements for International Application Entering U.S. Elected Office (EO/US)
page 1 of 7) 13-19

EXPRESS MAIL LABEL NO.: EV 927 568 381 US

WARNING:

Where the items being submitted to complete the entry of the international application into the national phase are subsequent to 30 months from the priority date the application is still considered to be in the international state and if mailing procedures are utilized to obtain a date the express mail procedure of 37 C.F.R. § 1.10 must be used (because international application papers are not covered by an ordinary certificate of mailing. 37 C.F.R. § 108(2)(xi).

NOTE:

Documents and fees must be clearly identified as a submission to enter the national stage under 35 U.S.C. § 371. Otherwise, the submission will be considered as being made under 35 U.S.C. § 111. 37 C.F.R. § 1.495(g).

DECLARATION OR OATH

NOTE: 37 C.F.R. § 1.495(c): "If applicant complies with paragraph (b) of this section before expiration of thirty months from the priority date but omits... the oath or declaration of the inventor (35 U.S.C. 371(c)(4) and § 1.497), if a declaration of inventorship in compliance with § 1.497 has not been previously submitted in the international application under PCT Rule 4.17 (iv) within the time limits provided for in PCT Rule 26ter.1, applicant will be so notified and given a period of time within which to file the ... oath or declaration in order to prevent abandonment of the application The payment of the surcharge set forth in § 1.492(e) is required for acceptance of the oath or declaration of the inventor later than the expiration of thirty months after the priority date."

I. (a) [x] No original declaration or oath was filed. Enclosed is the original declaration or oath for this application.

OR

(b) [] The declaration or oath that was filed was determined to be defective. A new original oath or declaration is attached.

NOTE:

For surcharge fee for filing declaration after filing date complete item IV(3)

NOTE:

- NOTE: Acceptable minimums in the declaration in an ordinarily filed U.S. application for identification of the specification to which it applies are:
- (A) application number (consisting of the series code and the serial number, e.g., 08/123,456);
- (B) serial number and filing date;
- (C) attorney docket number which was on the specification as filed;
- (D) title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or
- (E) title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date.

 Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration.

M.P.E.P. § 602, 8th ed.

NOTE:

Another minimum found acceptable in the declaration is the filing date (i.e., date of express mail) and the express mail number, useful where the serial number is not yet known. But note the practice where the express mail deposit is a Saturday, Sunday or holiday within the District of Columbia. 37 C.F.R. § 1.10(c).

NOTE:

See 37 C.F.R. § 1.41(a).

(complete as applicable)

	Attach	ed is a								
	(a)	[]	Statement by practitioner that papers attached to filed in PTO to get a filing date	declarati	on are a copy of those					
	(b)	[]	Statement that substitute specification contains	no new m	atter.					
	(c)	[]	Preliminary Amendment							
	(d)	[]	Submission of "Sequence Listing," computer reapertaining thereto for biotechnology invention amino acid sequence	dable cop containi	oy, and/or amendment ng nucleotide and/or					
			TRANSMITTAL OF ENGLISH TRANSLA OF NON-ENGLISH LANGUAGE PAPE							
II.	[]	interna	Submitted herewith is an English translation of the non-English language international application papers as originally filed. It is requested that this translation be used as the copy for examination purposes in the PTO. (See 37 C.F.R. 1.495(c))							
NOTE:		For fee j	For fee for processing a non-English application, complete item IV(4).							
NOTE:			A non-English oath or declaration in the form provided or approved by the PTO need not be translated. 37 C.F.R. \S 1.69(b).							
			FEES							
III.				v	•					
NOTE	: See 37 (C.F.R. § 1.	28(a).							
1.	Fees fo	Fees for search, exam or claims								
	[]		J.S. Search Report filed —\$400.00; entity—\$200.00		\$					
	[]	No Sea	arch Report —\$500.00; small entity —\$250.00		\$					
	[]	Exam	Fee not paid to U. S-\$200.00; small entity-\$10	00.00	\$					
	[]		a and Exam fee with U.S. WO or IPER conditions is fied—\$100.00; small entity—\$50.00	1	\$					
	[]		a and Exam fee with U.S. WO or IPER conditions led—\$0.00		\$					

01 FC:2614			200.00 BP	
03/12/2007	JBALINAN	00000063	10583334	
		b.	[] A separate refund request accompanies this paper.	14 (14 (14 (14 (14 (14 (14 (14 (14 (14 (
	·		 [] is attached. [] was filed on [] was made by paying the basic national fee as 	a small entity.
			(check and complete applicable items)	1.
		NOTE:	See 37 C.F.R. § 1.28(a).	
	IV.	a.	[] A Statement or Written Assertion that this filing is by	a small entity
•			SMALL ENTITY STATUS	
5			Total Fees	\$265.00
	3.	[]	processing fee set forth in 37 C.F.R. § 1.492(f) for acceptance of an English translation later than 30 months after the priority date—\$130.00	\$
٠			cessing fee in the next item 3 below is not subject to a reduction for small entit	y status.
			office—\$130.00; small entity—\$65.00	\$65.00
•		[x]	surcharge set forth in 37 C.F.R. § 1.492(e) for accepting the declaration later than 30 months after the priority date in filing an application in the U.S. as a designated	
	2.	Surcha	arge fees	·
		[]	multiple dependent claims(s) (37 C.F.R. § 1.492—\$360.00; small entity—\$180.00	\$
		[]	each claim in excess of 20 (37 C.F.R. § 1.492—\$50.00; small entity—\$25.00	\$
		[x]	Each independent claim in excess of 3 (37 C.F.R. § 1.492—\$200.00; small entity—\$100.00	\$200.00
		[]	37 C.F.R. 1.16(s)—\$250.00	\$

EXTENSION OF TIME

(complete (a) or (b), as applicable)

V.	The proceedings herein are for a patent application. Accordingly, the provisions of 37 C.F.R.									
§ 1.136	o(a) apply	_	Tem are for a par	.cm a	ippineation. 7	iccordingly,	the pro	V 131	ons of 37 C	.1 .10.
	(a)	Applicant petitions for an extension of time, the fees for which are set out in 37 C.F.R. § 1.17(a)(1)-(4), for the total number of months checked out below:								
		Extension (months)		Fee for other than small entity			Fee for small entity			
	[]	one mont	h	\$	120.00			\$	60.00	
	[]	two mont	hs	\$	450.00	-		\$	225.00	
	[]	three mor	iths	\$	1,020.00			\$.	510.00	
*	[]	four mon	ths	\$	1,590.00			\$	795.00	
	NOTE: The 2-month time period for reply to A Notice to File Missing Parts of an Application is not idented the Notice as a statutory period subject to 35 U.S. C. 133. Thus, extensions of time of up to 5 month. 37 CFR 1.136(a), followed by additional time under 37 CFR 1.136(b), when appropriate, are per MPEP 710.02(d)(c), 8th ed.									hs unde
	[]	five mont	hs	\$	2,160.00			\$	1,080.00	
						Fee:	.\$ <u>.</u> ;		·	
	If an ad	ditional ext	ension of time is	requ	ired, please o	onsider this	a petitio	on t	herefor.	
			(check and comp	olete	the next iten	ı, if applica	ble)		·	
[] An extension for months has already been secured. The fee paid the of \$ is deducted from the total fee due for the total months of extension now requested.								refor		
		Extension	fee due with this	requ	est \$					
					or					
(b)	[x]	petition is	believes that no e being made to pro the need for a po	ovide	e for the poss	ibility that a	pplican	t ha	nis condition s inadverter	nal ntly

TOTAL FEE DUE

VI.						
	The tot	cal fee due is: Completion fee(s) \$				
X777		PAYMENT OF FEES				
VII.	[x] []	Enclosed is a check in the amount of \$_265.00\$ Charge Account No. \(\frac{12-0425}{}\) in the amount of \$__\\ A duplicate of this request is attached.				
NOTE	: Fees sho	and be itemized in such a manner that it is clear for which purpose the fees are paid. 37 C.F.R. § 1.22(b).				
VIII.		AUTHORIZATION TO CHARGE ADDITIONAL FEES				
WARNING:		Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges if extra claims are authorized.				
NOTE:		"A written request may be submitted in an application that is an authorization to treat any concurrent of future reply, requiring a petition for an extension of time under this paragraph for its timely submission, a incorporating a petition for extension of time for the appropriate length of time. An authorization to charg all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).				
NOTE:		"Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonabl time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).				
	[X]	The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper and during the entire pendency of this application to Account No. 12-0425				
		[X] 37 C.F.R. § 1.492(a), (b) or (c) (search or exam fee) [] 37 C.F.R. § 1.492(b), (c), and (d) (presentation of extra claims)				
NOTE:		Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final actions.				
		 [X] 37 C.F.R. 1.16(s) (spec and drawing, each 50 pages over 100) [X] 37 C.F.R. § 1.17 (application processing fees) [X] 37 C.F.R. § 1.17(a)(1)-(5) (extension fees pursuant to § 1.136(a)). 				

Section 1.311(b) provides that an authorization to charge the issue fee (§ 1.18) to a deposit NOTE: account may be filed in an individual application only after the mailing of the notice of allowance. Accordingly, general authorizations to any fees and specific authorizations to pay the issue fee that are filed prior to the mailing of a notice of allowance will generally not be treated as requesting payment of the issue fee and will not be given effect to act as a reply to the notice of allowance. Applicant, when paying the issue fee, should submit a new authorization to charge fees, such as by completing box 6b on the current PTOL 85-B form. Where no reply to the notice of allowance is received, the application will stand abandoned notwithstanding the presence of general authorizations to pay fees or a specific authorization to pay the issue fee that were submitted prior to mailing of the notice of allowance. Where an attempt is made to pay the issue fee but an incorrect amount is submitted, § 1,311(b)(1), or where the Office's issue fee transmittal form (currently PTOL-85(B)) is completed by applicant ans submitted, § 1.311 (b)(2), in reply to a notice of allowance, an exception will be made. Such submissions will operate as a request to charge the issue fee to any deposit account identified in a previously filed (i.e., submitted prior to the mailing of the notice of allowance) authorization to charge fees, and will be allowed to act as payment of the correct issue fee. § 1.311(b). See also the change to § 1.26(b), Notice of September 8, 2000, Fed. Reg. 54603-54683, at 54646 and 54647.

[X] 37 C.F.R. § 1.492(e) and/or (f) surcharge fees for filing the declaration and/or an English translation of an international application later than 30 months from the earliest-claimed priority date.

WARNING:

It would be wise to always check this last authorization.

Refund any overpayment to deposit account 12-0425.

Reg. No.: 31,053

Tel. No.: (212)708-1915

Customer No.:00140

00140

PATENT TRADEMARK OFFICE

SIGNATURE OF PRACTITIONER

John Richards

(type or print name of practitioner)

P.O. Address

c/o Ladas & Parry LLP 26 West 61st Street New York, N.Y. 10023



United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS PO. Box 1450 Alexandria, Viginia 22313-1450 www.uspto.gov

U.S. APPLICATION NUMBER NO. FIRST NAMED APPLICANT ATTY. DOCKET NO.

10/583,334 · Francesco Santangelo

U0163256

INTERNATIONAL APPLICATION NO.

PCT/EP04/14359

140 LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NY 10023

RECEIVEDFEB **2 7** 2007

L & P LLP

PC1/EP04/14359

I.A. FILING DATE PRIORITY DATE

12/16/2004 12/19/2003

CONFIRMATION NO. 9753
371 FORMALITIES LETTER
OC0000000022580623

Date Mailed: 02/22/2007

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Indication of Small Entity Status
- Copy of the International Application filed on 06/16/2006
- Copy of the International Search Report filed on 06/16/2006
- Preliminary Amendments filed on 06/16/2006
- Information Disclosure Statements filed on 06/16/2006
- Request for Immediate Examination filed on 06/16/2006
- U.S. Basic National Fees filed on 06/16/2006
- Priority Documents filed on 06/16/2006

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Additional claim fees of \$200 as a small entity, including any required multiple dependent claim fee, are
 required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are
 due.
- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application
 by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$65 for a small entity in compliance with 37 CFR 1.27, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$265 for a Small Entity:

- \$65 Surcharge.
- Total additional claim fee(s) for this application is \$ 200
 - \$200 for 2 independent claims over 3.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web. https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

MAMIE P PERSON

Telephone: (703) 308-9140 EXT 227

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	. ATTY. DOCKET NO.
10/583,334	PCT/EP04/14359	U0163256

FORM PCT/DO/EO/905 (371 Formalities Notice)